

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

BRIGHAM AND WOMEN'S HOSPITAL, INC. and INVESTORS BIO-TECH, L.P.,	)	Civ. No. _____
	)	
Plaintiffs,	)	<b>JURY TRIAL DEMANDED</b>
v.	)	
PERRIGO COMPANY, L. PERRIGO COMPANY and CVS CAREMARK CORP.,	)	
	)	
Defendants.	)	
	)	
	)	

**COMPLAINT**

Plaintiffs Brigham and Women's Hospital, Inc. ("BWH") and Investors Bio-Tech, L.P. ("IBT") (collectively "Plaintiffs") file this Complaint for patent infringement against Perrigo Company and L. Perrigo Company (collectively "Perrigo") and CVS Caremark Corporation ("CVS") (all collectively "Defendants") under 35 U.S.C. § 271.

**BACKGROUND**

1. Pepcid Complete® contains a combination of antacid and famotidine, an acid-reducer, for the treatment of episodic heartburn. The development of Pepcid Complete® was the culmination of methods and formulations invented by Dr. M. Michael Wolfe—working at BWH—and taught and claimed in the patent-in-suit, United States Patent No. 5,229,137 (the "137 patent").

2. When Perrigo sought approval from the Food and Drug Administration ("FDA") to market its generic version of Pepcid Complete® pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(1), (j)(2)(A), (j)(7)(A), Perrigo certified against the patents listed in the FDA's list of Approved Drug Products with Therapeutic Equivalent Evaluations, commonly known as

the "Orange Book," including the '137 patent. Perrigo, however, did not make allegations that its proposed generic version of Pepcid Complete® would not infringe the relevant claims of the '137 patent in its paragraph IV certification. And when the makers of Pepcid Complete® sued Perrigo on another Orange Book patent, Perrigo successfully argued that the teachings in the earlier '137 patent invalidated the other patent.

3. Through this action, BWH seeks a reasonable royalty for Defendants' unauthorized and unlawful use of the innovations claimed in the '137 patent.

#### **THE PARTIES**

4. Plaintiff BWH is a Massachusetts hospital having a principal place of business at 75 Francis Street, Boston, Massachusetts 02115. BWH is a teaching affiliate of Harvard Medical School.

5. Plaintiff IBT is a Delaware limited partnership having a principal place of business at 111 Speen Street, Suite 303, Framingham, Massachusetts 01701. IBT is engaged in developing new technology and intellectual property relating to patient care.

6. On information and belief, defendant Perrigo Company is a Michigan corporation having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Company is a health care supplier that develops, manufactures and distributes generic over-the-counter ("OTC") and prescription pharmaceuticals throughout the United States, including in the Commonwealth of Massachusetts. The Company states on its website that it is the world's largest store brand manufacturer of OTC pharmaceutical products.

7. On information and belief, defendant L. Perrigo Company is a Michigan corporation having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010. L. Perrigo Company is a wholly owned subsidiary of Perrigo Company.

8. On information and belief, defendant CVS is a Delaware corporation having a principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS states on its website that it is the largest pharmacy health care provider in the United States. CVS, directly or through its subsidiaries, maintains a store locator website indicating that there are one or more CVS pharmacies in over 200 cities in the Commonwealth of Massachusetts.

**JURISDICTION AND VENUE**

9. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over each Defendant because each Defendant has, directly or through intermediaries, committed acts within Massachusetts giving rise to this action and/or has established minimum contacts with Massachusetts such that the exercise of jurisdiction would not offend traditional notions of fair play and justice.

11. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400.

12. Joinder of each Defendant is proper under 35 U.S.C. § 299 because a right to relief is asserted against all Defendants jointly and severally with respect to the same occurrences relating to the same accused product – Perrigo’s generic version of Pepcid Complete®, sold over the counter by CVS – and questions of fact common to all defendants will arise in the action.

**COUNT I: INFRINGEMENT OF U.S. PATENT NO. 5,229,137**

13. Plaintiffs incorporate by reference each and every allegation of paragraphs 1-12 of this Complaint, as though fully set forth herein.

14. On July 20, 1993, the '137 patent, entitled "Methods and Pharmaceutical Compositions for Treating Episodic Heartburn," was duly and legally issued. The '137 patent has recently expired.

15. A true copy of the '137 patent is attached hereto as Exhibit A.

16. BWH is and was at all relevant times the sole owner of the entire right, title, and interest in and to the '137 patent, including the right to sue and recover damages for any and all infringement thereof. IBT was at all relevant times the exclusive licensee of the '137 patent.

17. On information and belief, Perrigo holds Abbreviated New Drug Application ("ANDA") No. 77-355, directed to tablets containing 10 mg famotidine, 165 mg magnesium hydroxide, and 800 mg calcium carbonate (the "Perrigo generic product"). The Perrigo generic product is a generic version of the over-the-counter brand product Pepcid Complete®, which has the same amounts of the same active ingredients.

18. The '137 patent is listed in the Orange Book in conjunction with Pepcid Complete®, and claims 4 and 20 of the '137 patent cover Pepcid Complete®.

19. On information and belief, the Perrigo generic product is marketed to consumers in the United States under a variety of OTC store brands, including CVS' "Dual Action Complete." The Perrigo generic product was launched in or about the third quarter of 2008.

20. Perrigo's ANDA is the only approved ANDA for a generic version of Pepcid Complete®, as reflected in the Orange Book, and, on information and belief, Perrigo is therefore the source of all FDA-approved generic versions of Pepcid Complete® marketed in the United States, including accused products sold by CVS.

21. At all relevant times, Perrigo has had actual knowledge of the '137 patent. In connection with its ANDA filing, Perrigo filed a Certification of Invalidity or Non-Infringement of the '137 patent with the FDA. The statement of the factual and legal basis for Perrigo's Certification contains no allegation that the Perrigo generic product does not infringe claims 4 and 20 of the '137 patent.

22. On information and belief, at all relevant times CVS has had actual knowledge of the '137 patent or has been willfully blind to the patent and CVS' infringement thereof.

23. Prior to the expiration of the '137 patent, Defendants were directly infringing claims 4 and 20 of the patent by making, using, importing, selling, and/or offering to sell the Perrigo generic product.

24. Prior to the expiration of the '137 patent, Defendants were inducing infringement of claims 4 and 20 of the patent by intentionally encouraging acts of direct infringement by others, including but not limited to Defendants' customers, with knowledge that their acts were encouraging infringement. Defendants sold and distributed the Perrigo generic product with instructions for its use to treat gastric conditions, including episodic heartburn.

25. Prior to the expiration of the '137 patent, Defendants were contributing to infringement of claims 4 and 20 of the patent by offering to sell, selling, and/or importing the Perrigo generic product despite knowing that it is especially adapted for a use that infringes the '137 patent and that there is no substantial non-infringing use for the product.

26. As a result of the infringement of the '137 patent, Plaintiffs have been damaged and are entitled to be compensated for such damages, pursuant to 35 U.S.C. § 284, in an amount to be determined at trial, but no less than a reasonable royalty.

#### **WILLFUL INFRINGEMENT**

27. On information and belief, Defendants purposefully engaged in their infringing activities despite knowledge of an objectively high likelihood that their actions constituted infringement of one or more valid claims of the '137 patent, warranting an award of increased damages and a finding that this case is "exceptional" pursuant to 35 U.S.C. §§ 284 and 285.

#### **JURY TRIAL DEMAND**

28. Plaintiffs request a jury trial on all appropriate issues.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request that this Court enter:

1. A judgment in favor of Plaintiffs that Defendants have infringed the '137 patent;
2. A judgment and order requiring Defendants to pay Plaintiffs their damages, costs, expenses, and prejudgment and post-judgment interest for Defendants' infringement of the '137 patent as provided under 35 U.S.C. § 284;
3. An award to Plaintiffs of treble damages resulting from the knowing, deliberate, and willful nature of Defendants' prohibited conduct, as provided under 35 U.S.C. § 284;
4. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees; and
5. Any and all other relief as the Court deems just and proper.

BRIGHAM AND WOMEN'S HOSPITAL, INC.  
and INVESTORS BIO-TECH, L.P.

By their attorneys;

Dated: July 9, 2013

/s/Barbara L. Moore

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